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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/749,186 | 12/30/2003 | Richard Thomas | PA917US (51288-0053 US) | 9953 |
| 28390 7590 12/20/2006 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403 | | | EXAMINER GANESAN, SUBA | |
| | | | ART UNIT 3738 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 12/20/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/749,186 | Applicant(s) THOMAS, RICHARD | |
| | Examiner Suba Ganesan | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-17,19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/27/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 4, 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/16/2006.

Claim Objections

1. Claim 20 is objected to because of the following informalities: The claim depends on withdrawn claims 17 and 18 in the application. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-12, 14-16, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (U.S. Pat. No. 5342348).

Kaplan discloses a stent having a plurality of openings and an elongated polymer strand (16,14) woven longitudinally through the openings (fig. 2A). Examiner is interpreting the outer boundary of stent (2) to be a thin wall. Kaplan discloses that this strand is made of biodegradable polymer, for example poly(L-lactic acid) (col. 6 lines

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52-64). Kaplan also discloses an alternate polymer strand that is non-degradable, for example, strands made of ethylene-vinyl acetate copolymers (col. 7 lines 42-52).

Kaplan does disclose the use of a biomolecule such as a starch, col. 7, lines 53-58.

Kaplan further discloses a stent crimped onto a balloon (see fig. 6A and 6B). With respect to claims 14-16, Kaplan discloses methods of providing a therapeutic agent into a vessel lumen by implanting a stent with a woven polymer strand that has at least one therapeutic agent incorporated on it (see col. 10 lines 40-65). With respect to claim 25 and 26, it can be construed that Kaplan's strands form a sheath over a **portion** of the external surface of the stent and is can be an extruded polymer, col. 11, lines 58-61. .

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (U.S. Pat. No. 5342348) in view of Chouinard (U.S. Pat. No. 6156064).

Kaplan is explained above. However Kaplan does not disclose the stent is a self-expanding stent. Chouinard teaches the use of a self-expanding stent with filaments made of cellulose or collagen (see abstract and col. 8 lines 32-37). It would have been obvious to one of ordinary skill in the art to modify the stent of Kaplan according to the

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teaching of Chouinard to form it as a self-expanding stent, since self-expanding stents have smaller delivery profiles.

6. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (U.S. Pat. No. 5342348) in view of Mollison (U.S. Pat. No. 6015815).

Kaplan discloses same as above, including antibiotic coated strands (col. 7-8 lines 53-3). However Kaplan does not disclose this antibiotic being a tetrazole containing immunosuppressant macrolide antibiotic. Mollison teaches the use of macrolide immunomodulators containing tetrazole for the purpose of treating restenosis. It would have been obvious to one of ordinary skill in the art to modify the strands of Kaplan to include a tetrazole containing immunosuppressant macrolide antibiotic as taught by Mollison in order to treat restenosis. With regard to claim 20, Kaplan discloses a biodegradable polymer (col. 6 lines 52-64). Since claim 21 and 22 depend from a Markush grouping (claim 20), and the limitations of the Markush grouping have been met, claim 21 and 22 have not been further treated on the merits.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

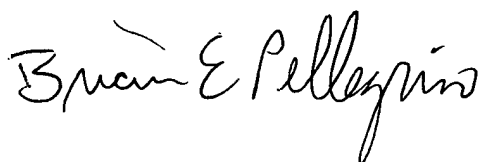
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 12/05/2006

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, reading "Brian E. Pellegrino". The signature is written in a cursive, flowing style with a large, stylized "P" and "L".